

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

AMB

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**Anti-Infective Drugs Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Anti-Infective Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on October 16, 2001, from 8:30 a.m. to 5 p.m.

*Location:* Hilton Washington DC North, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

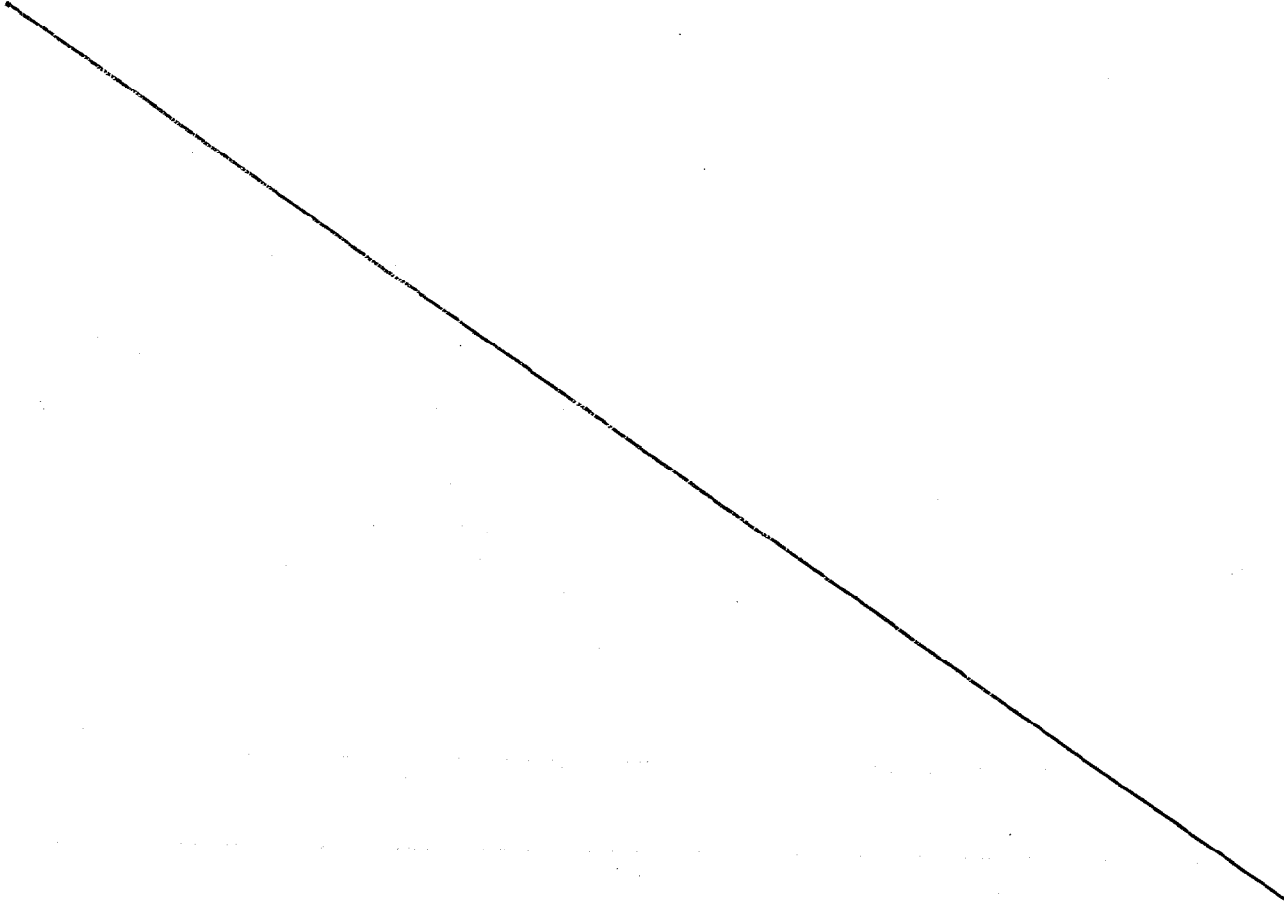
*Contact:* Thomas H. Perez, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6758, e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The committee will consider the safety and efficacy of Activated Protein C (human, recombinant, human kidney cells, new biologic license application (BLA) 125029), Eli Lilly & Co., for the treatment of severe sepsis.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 9, 2001. Oral presentations from the public will be scheduled on October 16, 2001, between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited.

Those desiring to make formal oral presentations should notify the contact person before October 9, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

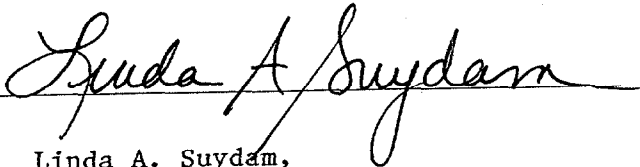
FDA regrets that it was unable to publish this notice 15 days prior to the October 16, 2001, Anti-Infective Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Anti-Infective Drugs Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 10/1/01  
October 1, 2001.



Linda A. Suydam,  
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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